SUBJECT: Standard Programming under the caBIG™ Program	SOP No.: IT-005
	Version No.: 2.0
	Effective Date: 12/11/2006
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Standard Operating Procedure – Standard Programming

This cover sheet controls the layout and components of the entire document.

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Department Approval:

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Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/05	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.

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1. Purpose

This Standard Operating Procedure (SOP) describes the process to assure that standard coding activities, which produce tables, listings, graphs, functions, packages and/or edit checks, are conducted in accordance with established industry conventions and are appropriately documented, tested and versioned in accordance with good programming practices and applicable International Conference on Harmonization (ICH) Statistical Principles for Clinical Trials Guidelines (E9). This SOP is to be used whenever new programs are required, or existing programs require modification during the set-up, conduct and/or reporting of clinical trial data.

2. Scope

This SOP applies to programs written to manipulate data throughout the data life cycle (e.g. procedures which calculate values, load data, etc.) in clinical trial research studies covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 All intended uses for standard or study specific programming or coding needs should be to be identified and documented in the study plan.

3.2 Industry standard programming conventions, based on application language requirements (e.g., SQL/PLSQL, SAS programming conventions, Visual Basic) should be employed.

3.3 All programs should be appropriately documented, tested and versioned according to NCICB configuration change management guidelines or practices.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	N/A	ICH Statistical Principles for Clinical Trials Guidelines (E9)
4.3	IT-003	SOP for Electronic Loading of Lab Data
4.4	IT-004	SOP for Electronic Loading of CDEs
4.5	N/A	Title 21 Part 312.32 Investigational New Drug Application, Sub Part B—Investigational New Drug Application (IND), IND Safety Reports
4.6	N/A	Title 21 Part 310.303 New Drugs, Sub Part D—Records and Reports, Continuation of long-term studies, records, and reports on certain drugs for which new drug applications have been approved

Section	SOP Number	Title
4.7	N/A	Title 21 Part 314.81(b)(2)(i) Applications for FDA Approval to Market a New Drug, Sub Part B—Applications, Other postmarketing reports, Summary
4.8	N/A	FDA Guidance for Industry-M4E: The CTD—Efficacy (August 2001)

5. Roles & Responsibilities

Role	Responsibility
Application's Standards Librarian	• Obtain analysis programs required for performing standard analyses defined in ISS and ISE plan. • Receive submitted newly created programs at a study level and review in order to assess whether they are reusable. • Promote all reusable new programs to the application's standards library for future use by other studies. • Manage timelines for promotion of programs to the application's standards library. • Quality-control application's standards library to ensure alignment to and consistency with latest updates.
Programmer	• Assist the Study Statistician in determining the programs required for the ISS and ISE analyses. • Write new analysis programs in line with specifications defined by the Study Statistician in charge. • Review and test analysis programs for functionality, utilizing identified test data. • Closely monitor the testing process throughout. • Resolve any analysis program malfunctions to ensure optimal program performance. • Modify analysis programs in line with input from Study Statistician and in line with SOPs on programming. • Update the application's standards library with newly created programs as requested by the Study Statistician.
Study Statistician	• Reuse analysis programs currently available on the application's standards library, as appropriate, when developing the relevant analysis programs. • Ensure that all relevant and required programs are created in line with analysis requirements identified in the statistical analysis plan (SAP). • Review newly added programs for consistency and completeness (against specified SAP requirements). • Review newly added programs for consistency and completeness (against specified ISS and ISE Plan

Role	Responsibility
	requirements).
Study Designer	• Ensure study design optimizes protocol requirements as well as study designs already available within the project. • Request all relevant input with regards to sites and investigators and patient populations. • Fully verify relevant lab conversions/units/ranges. • Optimally reuse already available derivations, validations and views programs in line with study requirements identified in the protocol from the application's standards librarian. • Inform the Study Statistician on which updates to the application's standards library validations, derivations and view programs may be required. • Fully test all additional derivations, validations and view programs at the study level and appropriately submit for activation to the application's standards librarian. • Extract SAS datasets from the clinical data management application in line with statistical requirements in an appropriate and timely manner. • Release database and communicate release to target audience.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Standard Programming	This document provides instructions for standard programming in the clinical data management application. It provides step-by-step guidance to assure that all programming is developed in a standard, quality manner.
2) Process Flow for Standard Programming	This document identifies the workflow activities, by role, for the steps identified in the Procedure Description for Standard Programming.